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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,433	01/15/2004	Horst Ulbricht	02481.1790-01	4111

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/757,433

Applicant(s)

ULBRICHT ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-6,8-14 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-6,8-14 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time, request for continued examination (RCE) under 37 CFR 1.114 and remarks, all filed 6/07/06. The amendment filed after the final office action is entered with the filing of the RCE. Claims 1, 17, 19, 21, 22, 24-29, 31-35, 38-42 and 44 are canceled by the present amendment. Claims 3-6,8-14 and 30 are thus pending.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/07/06 has been entered.

#### ***Regarding the Amendment to the specification***

2. The amendment filed 09/20/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure is as follows: Deletion or removal of "one or more" from paragraphs 10 and 22 of the specification introduces new matter to the disclosure. The specification as originally filed does not support deleting/removing "one or more" that identifies the extent of the nonvolatile constituents. The specification as originally filed does not state that the nonvolatile constituents are urea and hydrophilic polymer; specifically, paragraph 23 states

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“the amounts of urea are in each case based on the **nonvolatile constituents** of the use according to the invention and can be from 35 to 85 percent by weight, from 39 percent by weight to 83 percent by weight, from 46 percent by weight to 63 percent by weight, or from 55 percent by weight to 63 percent by weight.”

Applicant is required to cancel the new matter in the reply to this Office Action.

***Response to Arguments***

3. Applicant's arguments filed 3/14/2006 have been fully considered but they are not persuasive.

Regarding defining urea as non-volatile, it is noted that the definition goes against the chemistry of urea, which according to the twelfth edition of the Merck Index develops odor of ammonia (page 1683, item 10005).

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 3-6,8-14 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

The recitation that urea is non-volatile has no support in the as filed specification.

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This rejection can be overcome by amending the claims to be commensurate with the as filed specification.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 30 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2 202 743).

GB 2 202 743 discloses a varnish formulation that comprises urea, 10% by weight of the total composition and 41% by weight of the non-volatile constituents, EUDRAGIT at 12% by weight of the total composition and 50% by weight of the non-volatile constituents (Example 19). Varnish meets the limitation of a solution or liquid since varnish can be a liquid or solution and the prior art does not define the varnish as other than a liquid or solution. Furthermore, GB 2 202 743 discloses that the urea is about 1-20% by weight of the total composition, econazole is about 1-2% by weight of the total composition and the resin in the varnish is present at 10-20% by weight of the total composition (last paragraph of page 2, paragraph 1 of page 3, and paragraph 1 of page 5). The amounts above translate to about between 47-83% for the resin and about from 8 to about 64%. Cellulose derivatives (page 3, last paragraph bridging page 4) and

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polyvinylpyrrolidone/vinyl acetate polymer (last paragraph of page 4) are some of the film forming polymers used in the composition of the GB 2 202 743. GB 2 202 743 meets the limitations of the hydrophilic film-forming polymer in claims 30 and 8; the isopropyl or n-propyl alcohol meets the limitation of claims 30, 9 and 10. Primary or secondary alcohols utilized in the GB reference are ethanol or iso-propanol or n-propanol (page 3 at the third full paragraph). The GB reference specifically discloses using the composition to treat fungal infections of the nails or the surrounding tissues (page 5, 4<sup>th</sup> full paragraph) and also that the composition when applied hydrates the nail (page 2, first full paragraph).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3-6 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2 202 743.

The GB reference is described above. The GB reference discloses the treatment of nail fungus by using a composition comprising urea, hydrophilic polymer, alcohol and econazole. The GB reference fails to disclose the specific ratio/amounts of the components of the composition. However, one of ordinary skill would know how to optimize the composition to achieve the desired effect on the fungus and on the hydration of the nail. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the

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composition of the GB reference to treat nail fungus and to hydrate the nail, One having ordinary skill in the art would have been motivated to optimize the composition of the GB reference by employing amounts of ingredients effective to hydrate the nail for facilitate the active agent to be delivered at a deep level.

Upon further consideration, the Kraemer et al. (US 2002/0012749 A1) and the Smith (US 5,874,074) art are not used here.

Therefore, applicant's arguments with respect to Kramer and Smith are not addressed in view of the fact that rejections of the claims are not made over the art.

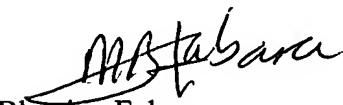
However, any of the previous prior art references may be reapplied if the claims are amended in the future to read on any of any of the previous prior art references that have been previously cited,

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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